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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,166

03/29/2006

Daniel Eric Lynch

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EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,166	Applicant(s) LYNCH ET AL.	
	Examiner SAMANTHA SHTERENGARTS	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. **Group I**, claims 1-7 drawn to photoluminescent compounds and protein detectors of the formula given in claim 1.
- II. **Group II**, claims 8-10 drawn to methods of using photoluminescent compounds and protein detectors of the formula given in claim 8.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

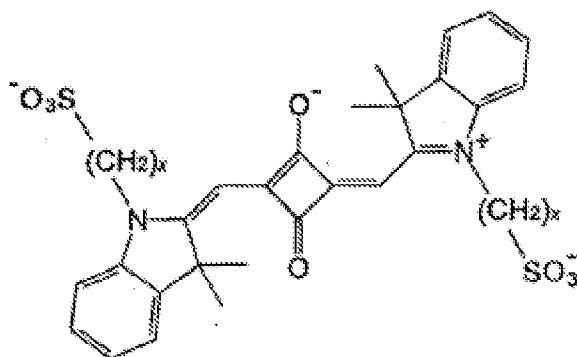
An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1).

With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

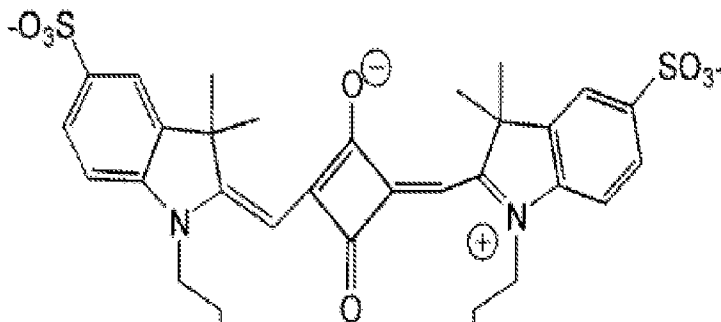
The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a)

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Group I lacks unity of invention since under 37 CFR 1.475: the technical feature corresponding to the claims is shown below:



This core technical feature is not a special technical feature because it fails to define a contribution over the prior art as can be seen in Singh (PCT/US00/18595), which discloses the same core in Claim 13, where x is 0. Below is a figure of the prior art from Singh.



Therefore, claims 1-10 are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical feature present fails to define a contribution over the prior art. The core technical feature that is being claimed is taught by the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention and should be limited to only a product or a method of use.

Furthermore, in regards to groups I and II, even if unity of invention under 37 CFR 1.475(a) is not considered lacking, which it is, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out the said process.

And according to 37 CFR 1.475(c): if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e): the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claims.

The claims, therefore, lack unity of invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. During a telephone conversation with Alan Young on 1/22/08 a provisional election was made without traverse to prosecute the invention of Group II, claims 8-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-7 withdrawn from further consideration by the examiner, 37 CFR 1.142 (b), as being drawn to a non-elected invention.

Information Disclosure Statement

In the information disclosure statement (IDS) submitted on March 29, 2006, the listing of non-patent references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each

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cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

All U.S. patent documents and foreign patent references were found to be in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 is enclosed herewith.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities:

- i. The specification lacks the appropriate headings for each section. (Cross-Reference to Related Applications, Background of the Invention, Summary of the Invention, Detailed Description of the Invention, Claims commencing on a separate sheet, Abstract of the Disclosure).
- ii. The figures on pages 10-12 of the specification must be submitted as drawings. The chemical formulas may remain in the specification; however, the graphs on pages 10 and 11 and the stick structure on page 12 must be removed. It would be remedial to delete the drawings from the specification and resubmit them as a separate drawings section, along with a Brief Description of the Drawings. See MPEP 608.02.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 rejected under 35 U.S.C. 112, second paragraph, because the phrase, “*including* a symmetrical skeletal structure of the general formula,” does not distinctly point out the subject matter that applicant is claiming as his invention. The term *including* literally means, *have as a part of, consider as part of something, add as part of something else*, etc. It is unclear to examiner if applicant is claiming a symmetrical skeletal structure of the general formula in Claim 8(a), or if applicant is claiming a symmetrical skeletal structure of the general formula in Claim 8(a) as being included in another, larger compound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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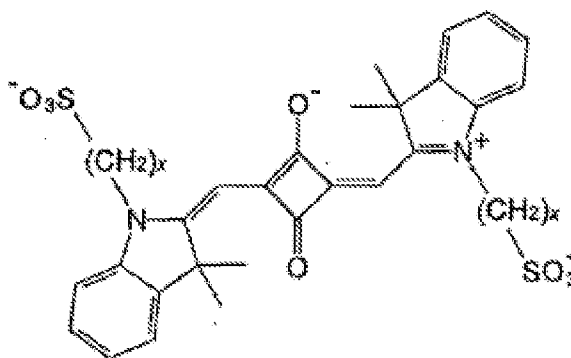
3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claim 8 rejected under 35 U.S.C. 103(a) as being obvious over Singh et al. (see WO 01/02374, drawings page 5).

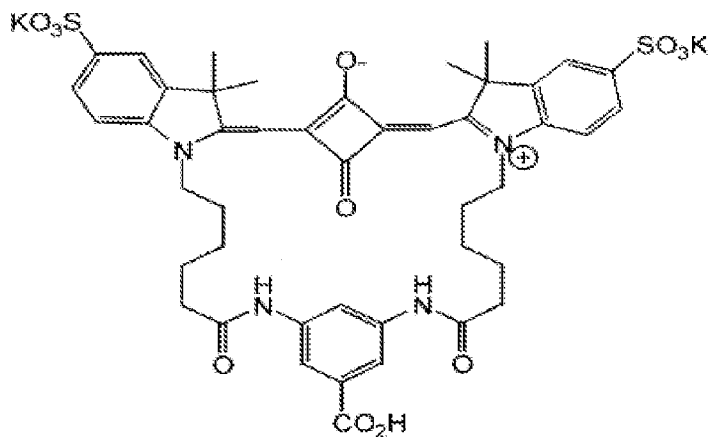
Determination of the scope and contents of prior art

See page 5 of drawings, middle structure of Fig. 2.

Ascertaining the differences between prior art and the instant claims

The instant claims teach a method for measuring the total dissolved protein content of a fluid sample by dissolving a photoluminescent compound including a symmetrical skeletal structure of the general formula below, in which x may represent any integer, and in which the phenyl rings may be substituted, in solution in water, at concentrations from 1×10^{-10} to 1 moles per liter.





Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness

To those skilled in the chemical art, one homologue is not an advance over an adjacent member of a homologous series. The reason for this is that one of ordinary skill, knowing the properties of one member of series, would know what properties to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). *In re Wood*, 199 USPQ 137 (C.C.P.A. 1978) and *In re Lohr*, 137 USPQ 548, 549 (C.C.P.A. 1963).

One of ordinary skill would be motivated, from the disclosure in the drawings of Singh et al., to make the modification required to arrive at the instant invention with reasonable expectation for success in this method. The motivation to make the compound of the claimed method would be to make additional compounds for the quoted method.

Thus, the instant claims are *prima facie* obvious over the teaching of the prior art.

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5. Claim 9 rejected under 35 U.S.C. 103(a) as being obvious over Merrill (Merril, Carl, R. "Gel-Staining Techniques." Methods in Enzymology 182(1990): 477-479.)

Determination of the scope and contents of prior art

See pages 477-479 disclosing the detection of electrophoretically separated proteins which teach limitations disclosed in the instant claims.

Ascertaining the differences between prior art and the instant claims

The instant claims teach a method for “detecting and/or quantifying proteins separated electrophoretically in a supporting matrix, either in the presence or absence of sodium dodecylsulfate (SDS),...comprising aqueous methanol and acetic acid,..”

The prior art teaches a technique for the detection of electrophoretically separated proteins (pg. 477, paragraph 4) in the presence of SDS (pg. 478, paragraph 2) comprising a solution containing 50% (v/v) methanol and 10% (v/v) acetic acid (pg. 479, paragraph 2).

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of

Obviousness

One of ordinary skill in the chemical art would be motivated to combine the disclosure of Merrill with the disclosure of Singh et al. due to their discussion of dyes and dye interactions. A person of ordinary skill in the pertinent art knows that these dyes can be employed in conventional methods of protein separation as disclosed in the instant claims.

Thus, the instant claims are *prima facie* obvious over the teaching of the prior art.

6. Claims 9 and 10 rejected under 35 U.S.C. 103(a) as being obvious over Harrington (Harrington, Michael G. "Elution of Protein from Gels." Methods in Enzymology 182(1990): 488.)

Determination of the scope and contents of prior art

See page 488 disclosing the use of polyacrylamide gel as a supporting matrix in the detection of electrophoretically separated proteins which are disclosed in the instant claims.

Ascertaining the differences between prior art and the instant claims

The instant claims teach a method for “detecting and/or quantifying proteins separated electrophoretically in a supporting matrix” wherein the supporting matrix is polyacrylamide, agrose or starch.

The prior art teaches a technique for the elution of proteins from gels wherein the various types of polyacrylamide gels can be employed (pg. 488, paragraph 2).

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of

Obviousness

One of ordinary skill in the chemical art would be motivated to combine the disclosure of Harrington with those of Merrill and Singh et al. due to their discussion of dyes and electrophoretic protein separation. A person of ordinary skill in the pertinent art knows that these dyes can be employed in conventional methods of protein separation as disclosed in the instant claims.

Thus, the instant claims are *prima facie* obvious over the teaching of the prior art.

Conclusion

7. No claims allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday, 8AM – 5PM Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang and Janet Andres can be reached on 571-27—0562 and 571-272-0867, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMANTHA SHTERENGARTS/
Examiner, Art Unit 4131

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4131